Application No.: 10/728,275 Docket No.: HO-P02726US2

AMENDMENTS TO THE CLAIMS

1. (currently amended) A method of treating a cardiovascular disease comprising the step of <u>parenterally or orally</u> administering to a subject an effective amount of a lactoferrin composition, to provide an improvement in the cardiovascular disease in said subject wherein the cardiovascular disease is atherosclerosis or vascular inflammation.

- 2. (canceled)
- 3. (original) The method of claim 1, wherein said lactoferrin composition reduces levels of circulating total cholesterol, low density lipoproteins (LDL), very low density lipoproteins (VLDL), or triglycerides in said subject.
- 4. (original) The method of claim 1, wherein said lactoferrin composition increases the levels of circulating high density lipoproteins (HDL) in said subject.
- 5. (original) The method of claim 1, wherein said lactoferrin composition reduces the levels of vascular inflammation in said subject.
- 6. (original) The method of claim 1, wherein said lactoferrin composition reduces circulating C-reactive protein (CRP) in said subject.
- 7. (original) The method of claim 1, wherein said lactoferrin composition reduces the proliferation of vascular smooth muscle cells in said subject.
- 8. (original) The method of claim 1, wherein said lactoferrin composition reduces the vascular spasm or vascular hyper-reactivity in said subject.
- 9. (original) The method of claim 1, wherein said lactoferrin composition promotes endothelial integrity or healing in said subject.
- 10. (original) The method of claim 1, wherein said lactoferrin composition is dispersed in a pharmaceutically acceptable carrier.

3

- 11. (original) The method of claim 1, wherein said lactoferrin is mammalian lactoferrin.
- 12. (original) The method of claim 11, wherein said lactoferrin is human or bovine.

25545504.1

Application No.: 10/728,275 Docket No.: HO-P02726US2

13. (original) The method of claim 1, wherein said lactoferrin is recombinant lactoferrin.

- 14. (original) The method of claim 1, wherein said lactoferrin composition comprises an N-terminal lactoferrin variant.
- 15. (original) The method of claim 14, wherein the N-terminal lactoferrin variant lacks at least the N-terminal glycine residue.
- 16. (original) The method of claim 15, wherein said N-terminal lactoferrin variant comprises at least 1% to at least 50% of the lactoferrin composition.
- 17. (canceled)
- 18. (currently amended) The method of claim 471, wherein parenterally is subcutaneously, intramuscularly, intraperitoneally, intravenously, intraarterially, intramyocardially, transendocardially, transepicardially, or intrathecally.
- 19. (canceled)
- 20. (currently amended) The method of claim 19–1 further comprising administering an antacid in conjunction with said lactoferrin composition.
- 21. (currently amended) The method of claim 19–1 further comprising administering the lactoferrin in a delayed release formulation.
- 22. (original) The method of claim 21 where the lactoferrin release occurs in the small intestine.
- 23. (original) The method of claim 21 where the lactoferrin release occurs in the large intestine.
- 24. (original) The method of claim 1, wherein the amount of the lactoferrin that is administered is about 1 ng to about 20 g per day.
- 25. (original) The method of claim 1, wherein the amount of the lactoferrin that is administered is about 0.1 g to about 5 g per day.

25545504.1 4

Application No.: 10/728,275 Docket No.: HO-P02726US2

26. (original) The method of claim 1, wherein said lactoferrin composition reduces the production or activity of pro-inflammatory cytokines.

- 27. (original) The method of claim 1 further comprising administering a lactoferrin composition in combination with an anti-cholesterol agent or an anti-inflammatory agent.
- 28. (original) The method of claim 27, wherein the anti-cholesterol agent is selected from the group consisting of cholesterol absorption inhibitors, bile acid sequestrants, nicotinic acid, fibric acids and HMG-coA reductase inhibitors.
- 29. (original) The method of claim 28, wherein the bile acid sequestrants are selected from the group consisting of cholestryramine, cholestipol and colesevalam.
- 30. (original) The method of claim 28, wherein the fibric acids are selected from the group consisting of gemfibrozil, fenofibrate and clofibrate.
- 31. (original) The method of claim 28, wherein the HMG-coA reductase inhibitors are selected from the group consisting of lovastatin, pravastatin, simvastatin, fluvastatin, atorvastatin and cerivastatin.

Claims 32-34 (canceled)

25545504.1 5